



4-32769P9



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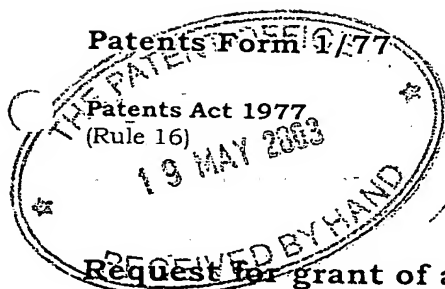
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2.	Patent application number (The Patent Office will fill in this part)	0311463.4		19 MAY 2003
3.	Full name, address and postcode of the or of each applicant (underline all surnames)	NOVARTIS NUTRITION AG MONBIJOUSTRASSE 118 3001 BERN SWITZERLAND 7143563001 SWITZERLAND		
	Patent ADP number (if you know it)			
	If the applicant is a corporate body, give the country/state of its incorporation			
4.	Title of invention	Connector Device		
5.	Name of your agent (If you have one) "Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)	B.A. YORKE & CO. CHARTERED PATENT AGENTS COOMB HOUSE, 7 ST. JOHN'S ROAD ISLEWORTH MIDDLESEX TW7 6NH		
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B.A. Yorke & Co.

19th May 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

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020 8560 5847

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### Connector Device

The present invention relates to a connector device or adaptor, e.g. a sterile connector device or adaptor, allowing connection between the feeding line of an enteral, e.g. nutritional, administration set and a laminated paper packaging system, such as Tetra Brik®, containing medical or nutritional fluids or compositions which may be enterally administered to a patient. Such a connector device allows flow of a composition contained in the laminated paper packaging system to the enteral administration set through the connector device.

Many individuals in hospitals or nursing homes cannot orally take nourishment or medication. These individuals, or medical patients, typically receive medical flowable materials, e.g. fluids, containing the required nourishment and/or medication enterally via a patient feeding line of an enteral administration set that is connected to a packaging system containing such medical or nutritional flowable materials, e.g. fluids. These medical or nutritional flowable materials, e.g. fluids, are commonly packaged in flexible packaging systems, such as containers, for example flexible pouches. For economical and other reasons, such pouches may be disadvantageous.

Millions of laminated paper packaging systems, such as Tetra Brik®, are used in the food industry. They provide a convenient cost-effective and lightweight paperboard container, for every type of pourable, e.g. liquid, product. They exist in a myriad of sizes, from 0.2 liter to 1.5 liter, or even larger. Because they are opaque, they are perfect for light-sensitive enterally administrable compositions, for example enterally administrable compositions containing certain vitamins. Typically, medical fluids that are administered to a patient need to be sterile. Laminated paper packaging systems may be sterilized, and therefore may keep even the most perishable liquid foods fresh and nutritious for months, without refrigeration or added preservatives. Finally, the laminated paper packaging systems may be aseptically and air tightly closed, preventing contaminants and/or oxygen from entering the container. Such laminated paper packaging systems may be advantageously used to contain pharmaceutical or nutritional compositions, e.g. enteral medical or nutritional fluids.

However, the existing enteral administration sets are not adapted to being connected, e.g. directly connected, to the existing laminated paper packaging systems. Consequently, medical or nutritional compositions, e.g. fluids, have to be poured into an intermediate

container which is then connected to the feeding line of an enteral administration set. This is inconvenient for patients and medical personnel. Moreover sterility is difficult to ensure.

5 In one aspect the present invention provides a connector device or adaptor suitable for use with an enteral administration set, e.g. the feeding line of an existing enteral administration set, and an laminated paper packaging system.

Such enteral administration sets, e.g. feeding lines, e.g. tube feeding lines of enteral administration sets, and existing laminated paper packaging systems, are well-known to one skilled in the art. For example, enteral administration sets are known and commercially available e.g. from Abbott, Fresenius, Nutricia, Sherwood Medical Company, B: Braun Melsungen or Novartis Nutrition Corporation, e.g. under the trade name Compat® commercially available from Novartis Nutrition Corporation (Minneapolis, Minnesota). Examples of known and commercially available laminated paper packaging systems are 15 Tetra Brik®, Tetra Pak®, Tetra Brik Aseptic®, Tetra Prisma®, Tetra Recart®, Tetra Top®, Tetra Square®, available from Tetra Pak Switzerland AG, as well as Elopak®, Combiblok®, Pure Pak®, or those available from Toppan.

20 In another aspect of the invention, there is provided a connector device suitable for connecting, e.g. directly connecting, an enteral administration set, e.g. the feeding line of an enteral administration set, to a laminated paper packaging system. Such a connector device may provide a sealable, e.g. a liquid-tight, connection between the enteral administration set and the laminated paper packaging system.

25 In a further aspect of the invention, there is provided a connector device which provides an air-tight, e.g. oxygen-tight, and/or sterile connection between the enteral administration set and the laminated paper packaging system.

30 In yet a further aspect of the invention, there is provided a closed system consisting of a connector device for an enteral administration set, e.g. the feeding line of an enteral administration set, and/or a laminated paper packaging system, wherein the connector device provides an oxygen-tight and/or sterile connection directly to the laminated paper packaging system and/or the enteral administration set.

The connector device according to the invention may be reusable or disposable for single usage.

In another aspect of the invention there is provided a connector device adapted to fit, e.g. sealably fit, to a laminated packaging system, and to simultaneously open, directly or indirectly, the laminated paper packaging system when being connected, e.g. sealably connected, thereto. Such a connector device may be adapted to be connected, e.g. directly connected, to an enteral administration set, e.g. the feeding line of an enteral administration set.

In a further aspect of the invention there is provided a connector device for a laminated paper packaging system comprising a closure system, e.g. a barrier layer, which connector device comprises at least one means adapted for simultaneously opening, e.g. breaking, the closure system of the laminated paper packaging system when being connected, e.g. sealably connected, thereto. Such a connector device may be adapted to be connected, e.g. directly connected, to an enteral administration set, e.g. the feeding line of an enteral administration set.

In another aspect of the invention there is provided a connector device for an enteral administration set and a laminated paper packaging system comprising:

- (a) a first section adapted to fit, e.g. sealably fit, to the laminated paper packaging system, and
- (b) a passageway to allow the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging through the connector device, and optionally
- (c) a second section adapted to fit, e.g. sealably fit, to the enteral administration set, e.g. a thread wall portion, and optionally
- (d) at least one venting means, e.g. air passageway, to allow, e.g. selectively allow, outside air to flow into the connector device and/or the laminated paper packaging system, e.g. when the connector device is connected, e.g. sealably connected, to the laminated paper packaging system, which venting means optionally comprise means to allow filtration of the air, e.g. means to allow filtered air to flow, and optionally,
- (e) at least one means adapted to prevent the flow of the composition through the venting means.

In a further aspect of the present invention there is provided a connector device for an enteral administration set and a laminated paper packaging system comprising a closure system, e.g. a barrier layer, such a connector device comprising:

- 5 (a) at least one means adapted to fit, e.g. sealably fit, to the laminated paper packaging system, e.g. in the area of the closure system, and
- (b) at least one means, e.g. passageway, e.g. fluid passageway, to allow the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging through the connector device, and optionally
- 10 (c) at least one means adapted to provoke directly or indirectly the opening, e.g. breaking, of the closure system of the laminated paper packaging system, in particular when connected, e.g. sealably connected, to the laminated paper packaging system, and optionally
- (d) at least one venting means, e.g. air passageway, to allow, e.g. selectively allow, outside air to flow into the connector device and/or the laminated paper packaging system,
- 15 e.g. when the connector device is connected, e.g. sealably connected, to the laminated paper packaging system, which venting means optionally comprise means to allow filtration of the air, e.g. means to allow filtered air to flow, and optionally,
- (e) at least one means adapted to prevent the flow of the composition through the venting means, and optionally
- 20 (f) at least one means adapted to fit, e.g. sealably fit, to an enteral administration set, e.g. to the feeding line of an enteral administration set.

In one embodiment of the invention, the connector device may consist of one unit, e.g. made entirely of a single material, for example an opaque or transparent material. In another  
25 embodiment of the invention, the connector device may be a kit-of-parts connector device, i.e. made of independent sections, e.g. made of different material, adapted to be assembled, e.g. just before use, such as a section adapted to fit, e.g. sealably fit, to a laminated paper packaging system and/or a section adapted to fit, e.g. sealably fit, to the enteral administration set, e.g. a thread wall portion. The section of such a kit-of-parts connector  
30 device which is adapted to fit, e.g. sealably fit, to the feeding line of an enteral administration set may be connected, e.g. permanently or irreversibly connected to the enteral administration set. According to the invention, the section of such a kit-of-parts connector device which is adapted to fit, e.g. sealably fit, to the laminated paper packaging system may be connected, e.g. permanently or irreversibly connected to the laminated paper packaging



system. Optionally such a section of a kit-of-parts connector device may further comprise at least one venting means, e.g. air passageway, to allow, e.g. selectively allow, outside air to flow into the connector device and/or the laminated paper packaging system, which venting means optionally comprise means to allow filtration of the air, e.g. to allow flow of filtered outside air.

In another aspect of the present invention there is provided a device comprising an enteral administration set and a connector device connected, e.g. sealably connected, e.g. permanently or irreversibly connected, thereto for a laminated paper packaging system comprising a closure system, e.g. a barrier layer, i.e. adapted to be connected, e.g. sealably connected, to the laminated paper packaging system. Optionally such a device may comprise at least one means adapted to provoke directly or indirectly the opening, e.g. breakage, of the closure system of the laminated paper packaging system when connected, e.g. sealably connected, thereto. Such a device may further comprise at least one venting means, e.g. air passageway, to allow, e.g. selectively allow, outside air to flow into the connector device and/or the laminated paper packaging system, e.g. when the connector device is connected, e.g. sealably connected, to the laminated paper packaging system, which venting means optionally comprise means to allow filtration of the air, e.g. to allow flow of filtered outside air.

In yet another aspect of the present invention there is provided a device comprising a laminated paper packaging system comprising a closure system, e.g. a barrier layer, and a connector device connected, e.g. sealably connected, e.g. permanently or irreversibly connected, thereto for an enteral administration set, i.e. adapted to be connected, e.g. adapted to be sealably connected, to an enteral administration set. Optionally such a device may comprise at least one means adapted to provoke directly or indirectly the opening, e.g. breakage, of the closure system of the laminated paper packaging system. Such a device may further comprise at least one venting means, e.g. air passageway, to allow, e.g. selectively allow, outside air to flow into the connector device and/or the laminated paper packaging system, e.g. when the connector device is connected, e.g. sealably connected, to the laminated paper packaging system, which venting means optionally comprise means to allow filtration of the air, e.g. to allow flow of filtered outside air.

In another aspect of the invention, there is provided a connector device and a device comprising at least one means adapted to prevent the flow of the composition through the venting means when the connector device or the device is connected, e.g. sealably connected, to the laminated paper packaging system and/or the enteral administration set.

5 According to the invention, the connector device and the device as hereinabove described may comprise means, e.g. a tamper-proof system, adapted to provide visible tamper signal indicating that the connector device, or the device, has been connected to, e.g. sealably connected to, and/or has opened the laminated paper packaging system.

10 In yet a further aspect of the present invention there is provided an enteral administration set, e.g. a feeding line of an enteral administration set, connected, e.g. sealably connected, to a laminated paper packaging system, e.g. of the type Tetra Brik® or Tetra Pak®, comprising a nutritional or medical composition through the connector device as  
15 hereinabove described.

The accompanying drawings, which are incorporated into and constitute part of the specification, illustrate exemplary embodiments of the present invention.

20 FIG. 1 is an exploded cross-sectional view of a connector device connected to a feeding line of an enteral administration set and a laminated paper packaging system in accordance with an embodiment of the present invention;

FIG. 2 is an enlarged cross-sectional view of the connector device depicted in FIG. 1.

25 FIG. 3 is a cross-sectional view of a second embodiment of a connector device adapted to indirectly open a laminated paper packaging system when connected thereto, in accordance with one embodiment of the present invention.

FIG. 4 is an exploded cross-sectional view of a connector device for connection to a laminated paper packaging system in accordance with a further embodiment of the present invention.

30 FIG. 5 is a cross-sectional view of the steps for connection of the connector device depicted in FIG. 4 to a laminated paper packaging system.

FIG. 6 is a cross-sectional view of further embodiments of connection of connector devices to laminated paper packaging systems.

The connector device according to the invention permits the connection between an enteral administration set, e.g. the feeding line of an enteral administration set, and a laminated paper packaging system. The device permits the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system into the enteral administration set through the connector device, when the connector device is connected, e.g. sealably connected, thereto. As used herein, the term "sealably connected" refers to a connection which temporally or permanently may prevent leakage of the composition when the composition is flowing through the connector device, e.g. a liquid-tight connection.

According to the invention, the connection between the connector device of the invention and the laminated paper packaging system and/or an enteral set may be air-tight, e.g. oxygen-tight, and/or sterile.

As used herein, the term "enteral administration set" encompasses all components of the feeding line located between the connector device as hereinabove described, and the patient, for example the tube feeding line, and optionally a plastic bag sealably connected to the tube feeding line. Such a plastic bag may be substantially collapsible. It may further be substantially transparent. It may also be vented or contain air, e.g. sterilized air.

In one embodiment of the invention, such a plastic bag, e.g. a transparent and/or sterilized plastic bag, may be reversibly or permanently, e.g. irreversibly, connected, to the connector device. The irreversible connection of the connector device to the plastic bag may for example be made by methods including, but not limited to, heat induction, ultrasonic welding and friction welding or any other methods as known in the art.

In another embodiment of the invention, the enteral administration set may include a gravity set, e.g. with roller clamp. Alternatively, or in addition to the gravity set, the enteral administration set may include a pump set, e.g. of the type Compat® from Novartis Nutrition Corporation (Minneapolis, Minnesota).

Referring to FIGs. 1, 2, 3, 4, 5, and 6, the connector device (1) may be sealably connected to an enteral administration set, e.g. the feeding line (2) of an enteral administration set (3), and to a laminated paper packaging system (4). The connector device may comprise: a section (5) which is adapted to fit, e.g. sealably fit, to the feeding line (2) of

the enteral administration set (3); on the opposite side a section (6) adapted to be connected, e.g. sealably connected, to the laminated paper packaging system (4); means, e.g. passageway, e.g. fluid passageway (5a), allowing flow of the composition through the connector device; and optionally venting means (7), e.g. valve system, positioned such as to allow, e.g. selectively allow, the outside air to penetrate into the laminated paper packaging system when the connector is connected, e.g. sealably connected, to the enteral administration set and/or to the laminated paper packaging system (4). According to the present invention, the venting means (7) may also comprise means, e.g. air filter (9), e.g. bacterial filter, to allow filtration of the air and prevent non-filtered air or contaminants, e.g. bacteria, from entering the feeding line and/or the laminated paper packaging system and/or the connector device. It will be appreciated that such venting means, e.g. valve system and optionally air filter, may be positioned in the feeding line of the enteral administration set, or in the laminated paper packaging system. Preferably, such venting means, e.g. valve system and optionally air filter, are positioned in the connector device, even more preferably in section (6) of the connector device which is adapted to be connected to the laminated paper packaging system.

In one aspect of the invention, the venting means may comprise an air passageway (7a) allowing air, e.g. filtered air, to penetrate into the laminated paper packaging system, optionally without penetrating into the fluid passageway (5a). The passage of the composition contained in the laminated paper packaging system from the laminated paper packaging system through the air passageway (7a) may be prevented, e.g. by a flexible membrane positioned adjacent to the inner opening of the air passageway, as described for example in US 4,997,429, which is incorporated herein by reference.

Such venting means are known and commercially available in existing enteral feeding sets, e.g. of the type Compat® from Novartis Nutrition Corporation (Minneapolis, Minnesota).

In one embodiment of the invention, the air passageway (7a) is substantially in the center of the connector device.

Section (5) of the connector device adapted to the enteral administration set (3) may be sealably connected to the feeding line (2) by friction fit, e.g. through means capable of interlocking, linking or slotting-in (8a) with compatible elements in the feeding line, e.g.

through a thread (8), e.g. screw thread. For example, a snap-fit assembly may be used to sealably connect the connector device to the feeding line (2). A circumferential tab section projecting from the section of the connector device adapted for connecting to the feeding line may engage a rim at the end of the feeding line, sealably connecting the connector device to the feeding line. After engagement, e.g. linking, slotting-in or interlocking, the connector device may be further adhered to the feeding line, e.g. by sealing, e.g. sonic welding, or by glue. According to the invention, the part of the feeding line which is suited to be connected, e.g. linked, slotted-in or interlocked, to the connector device of the invention may not have a sharp edge or spike, e.g. may not be substantially tapered.

In one preferred embodiment of the invention, section (5) of the connector device adapted to the enteral administration set (3) comprises a linking, e.g. slotted-in, section (8a), in which the extremity of the feeding line, e.g. substantially not tapered, may be fitted, e.g. tightly fitted, such as by friction fit.

In a further embodiment of the invention, the connector device, e.g. section (5) of the connector device may be sealably connected, e.g. permanently or irreversibly connected, to the feeding line by sealing, e.g. sonic welding, or by glue (not shown).

In yet a further embodiment of the invention, the feeding line of the enteral administration set may comprise a portion with an enlarged diameter, e.g. a diameter larger than the diameter of the rest of the feeding line, e.g. a drip chamber, in order for example to allow fluid to be seen flowing from the laminated paper packaging system. Such an enlarged portion of the feeding line, e.g. drip chamber, may be substantially transparent. It may further be positioned near the connector device or may be the portion of the feeding line which is directly connected, e.g. interlocked or linked, to the connector device (not shown).

For the purpose of the present invention, the term "compositions" encompasses nutritional and medical compositions, e.g. nutritional and medical flowable materials, e.g. fluids, and in particular enteral compositions. According to the invention, these compositions are contained in a laminated paper packaging system.

The laminated paper packaging system (4) according to the invention may be for example of the type Tetra Brik®, Tetra Brik Aseptic®, Tetra Pak®, Tetra® Prisma, Tetra

Recart®, Tetra Square®, Tetra Top®, Elopak®, Combiblok®, Pure Pak®. According to the invention, the laminated paper packaging system may be from about 0.125 liter to about 2 liters volume, preferably from about 0.200 liter to about 1 liter volume. Most preferred sizes include about 0.200, about 0.250 and about 1 liter.

5

Such laminated paper packaging systems may comprise layers of fibrous material, such as paper or cardboard, which are coated on either side with a thermoplastic material such as polyethylene. On the side of the laminated paper packaging material which is destined to be in contact with the composition, there may be also a layer of barrier material, such as e.g. aluminum foil, which may also be coated with a thermoplastic layer. Such laminated paper packaging systems are disclosed for example in US 6,223,924 or EP1088765, which are hereby incorporated by reference. Techniques to sterilize such laminated paper packaging systems are known to one skilled in the art. Packaging machines have been developed to aseptically fill and seal such laminated paper packaging systems, e.g. sterilized laminated paper packaging systems, with sterilized food products or compositions.

10

Such laminated paper packaging systems may comprise a reduced thickness portion, e.g. a portion where a hole is formed through some of the layers of the laminated paper packaging materials, and where one or more aluminum and/or polyethylene barrier layers extend over the hole (17). Such a reduced thickness portion may be closed, e.g. liquid or air-tightly closed, e.g. aseptically closed, by a closure system (10). Alternatively the laminated paper packaging systems may comprise a hole not covered by any layers of the laminated paper packaging materials. Such laminated paper packaging systems may also be closed, e.g. liquid or air-tightly closed, e.g. aseptically closed, by a closure system (10).

20

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According to the invention, the term "closure system" refers to a removable or breakable closure system. As used herein the term "breakable" encompasses breakable by rupturing, perforating and/or tearing, e.g. completely or partially, providing an opening in the closure system of the laminated paper packaging system, sufficiently extended to permit composition to flow from the laminated paper packaging system through the connector device into the feeding line.

30

The closure system according to the invention may consist of a barrier layer (10) removable or breakable in some manner, for example by removal or by penetration, e.g. a seal, e.g. a foil seal, e.g. in form of a pull tab to be removed, e.g. peeled off, before use (18). In one embodiment of the invention such a closure system may be liquid-tight or airtight, e.g. may keep the composition contained in the laminated paper packaging system aseptic. Preferably, the barrier layer, e.g. the foil seal, is adhesively hot sealed, e.g. aseptically sealed, to the laminated paper packaging system, e.g. by flowing a heated foodgrade hot melt adhesive between the barrier layer and the laminated paper packaging system, where the barrier layer, e.g. the foil seal, is in contact with the laminated paper packaging system. This closure system, e.g. the barrier layer, may be opaque. It may also be made of a material that has no or low permeability to air, e.g. to oxygen. Suitable barrier layers are known to one skilled in the art and include, but are not limited to, for example, polymeric membranes, aluminum foil or thin plastic. It will be appreciated that one skilled in the art is fully enabled to select a suitable material.

15

The closure system of the laminated paper packaging system, may also consist of a frame-like member (11), integrated within the laminated paper packaging system, preferably affixed thereto, circumscribing the barrier layer. The frame-like member of the laminated paper packaging system may be of the type associated with spin® cap or stream® cap, available e.g. from Tetra Pak Switzerland AG. Such frame-like members are known to one skilled in the art, and are described e.g. in EP0947433, EP1088765, EP1262412, US 6,382,462, US 6,422,412 or US 6,223,924, which are hereby incorporated by reference. The frame-like member may be integrated within the laminated paper packaging system by techniques known to one skilled in the art, e.g. by application of hot melt adhesive, microflame welding or laser welding. Such a frame-like member (11) may be closed by a second barrier layer, e.g. a foil, e.g. an aluminum foil, removable therefrom. In another embodiment of the invention, the frame-like member (11) may be closed by a standard cap, e.g. a reclosable cap, e.g. screw or push cap. In this case, access to the barrier layer covering the opening of the laminated paper packaging system may be made after removing the cap from the frame-like member.

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According to the present invention, the connector device (1) may be connected to the laminated paper packaging system (4) through the frame-like member (11) thereof, e.g. through an internal thread (12a), e.g. screw thread, of the connector device interacting with

an external thread (12b), e.g. screw thread, of the frame-like member (11), e.g. as described in EP1088765, which is hereby incorporated by reference, or any other suitable structure known in the art.

5 In one embodiment of the invention, section (6) of the connector device of the invention is adapted to fit to a laminated paper packaging system, has a diameter, e.g. internal diameter, comprised between about 1.0 cm and about 3.5 cm, preferably between about 1.3 cm and about 3.0 cm, more preferably between about 1.5 cm and about 2.5 cm and even more preferably between about 1.8 cm and about 2.3 cm. The most preferred diameter, e.g.  
10 internal diameter of the section of the connector device adapted to fit to the laminated paper packaging system is about 2 cm, e.g. 2.1 or 2.2 cm.

In one embodiment of the invention, the connector device (1) comprises an opening system (13), e.g. a breaking system, adapted to open, e.g. break, the closure system, e.g.  
15 barrier layer (10), of the laminated paper packaging system (4), e.g. creating an opening in the closure system to allow flowing of the composition from the laminated paper packaging system. This opening, e.g. breaking, system may comprise one or more cutting means, e.g. spikes (14), cutting teeth, cutter or any other suitable structure known to one skilled in the art.

20 In another embodiment of the invention, the cutting means are projecting means. The length, position and number of the cutting means, e.g. projecting means, may be adapted to open, e.g. break, the closure system of the laminated paper packaging system when the connector device is connected, e.g. sealably connected, thereto, e.g. screwed onto the frame-like member (11) of the closure device of the laminated paper packaging system.  
25 Alternatively the cutting means, e.g. projecting means, may extend beyond the bottom of section (6) of the connector device adapted to be connected to the laminated paper packaging system.

According to the invention, the opening, e.g. breaking, system of the connector device  
30 may be offset from the center, e.g. center axis, thereof.

In another embodiment of the invention, the opening, e.g. breaking, system of the connector device may be placed in the center of the connector device. For example, the opening, e.g. breaking, system of the connector device may be in prolongation from, e.g. an



extension of, the section of the connector device adapted to be connected to the feeding line of the enteral administration set.

According to the invention, the opening, e.g. breaking, system of the connector device  
5 may be hollow, e.g. may include a fluid passageway permitting composition flowing from the laminated paper packaging system through the connector device into the enteral administration set, e.g. the feeding line of the enteral administration set.

In another embodiment of the invention, the opening, e.g. breaking, system of the  
10 connector device may consist of a tubular member provided inside the connector device and adapted to be engaged with the frame-like member (11) of the laminated paper packaging system, e.g. by comprising external threads capable of connecting internal threads present in the frame-like member (11), and to move in direction of the closure device when the connector is connected, e.g. sealably connected, to the laminated paper packaging system.  
15 Such a tubular member may comprise, e.g. on its lowermost edge, at least one cutting means, e.g. cutter, e.g. cutting tooth, adapted to break the closure system, e.g. the barrier layer (10), of the laminated paper packaging system, upon engagement of the tubular member with the frame-like member. Such opening systems are known to one skilled in the art, e.g. associated with stream® cap or spin® cap, available e.g. from Tetra Pak  
20 Switzerland AG, e.g. as described in EP0947433, EP1088765 or EP1262412, which are hereby incorporated by reference.

In a further embodiment of the invention, the opening, e.g. breaking, system of the  
connector device may be moved in direction of the closure device of the laminated paper  
25 packaging system through transmission means associated with the connector device, e.g. as described in EP1088765, which is hereby incorporated by reference.

The opening, e.g. breaking, system of the connector device may directly open, e.g.  
break, the closure system, e.g. the barrier layer (10), of the laminated paper packaging  
30 system, when connecting, e.g. sealably connecting, the connector device (1) thereto. Such a contact may be made by pressing the connector device (1) to the laminated paper packaging system (4), or alternatively by screwing it, onto the frame-like member (11) of the laminated paper packaging system.

In another embodiment of the invention, the closure system, e.g. barrier layer (10), of the laminated paper packaging system (4) may be opened, e.g. broken, by an opening, e.g. breaking, system (15) associated with, e.g. incorporated into, the frame-like member (11) of the laminated paper packaging system (4). Such an opening, e.g. breaking, system may be  
5 movable, e.g. from a first position where it does not open, e.g. not break, the closure system of the laminated paper packaging system, e.g. where it is not into contact with the closure system, to a second position where it opens, e.g. breaks, the closure system, e.g. where it protrudes below the frame-like member (11). Preferably the opening, e.g. breaking, system may be formed integrally with an elastic hinge. The elastic hinge may be formed integrally  
10 with the frame-like member. Such opening, e.g. breaking, systems associated with laminated paper packaging systems are known in the art and include, but are not limited to, for example opening, e.g. breaking, systems connected to the frame-like member associated with caps, e.g. twist-off or screw caps, e.g. of the type spin® cap or stream® cap, or snap-on caps. The opening, e.g. breaking, system may comprise or consist of opening means, e.g. breaking  
15 means, e.g. projecting means, e.g. spikes (14), cutting teeth, cutter. Preferably the opening system of the laminated paper packaging system (4) is of the type of the breaking system connected to the frame-like member associated with spin® cap or stream® cap, e.g. as described in US 6,223,924, EP1088765, EP0947433, EP1262412, US 6,382,462 or US 6,422,412, which are hereby incorporated by reference.

20 According to the present invention, the opening, e.g. breaking, system of the laminated paper packaging system (4) may be indirectly opened, e.g. triggered, by connecting, e.g. sealably connecting, the connector device, i.e. section (6) of the connector device adapted to be connected to the laminated paper packaging system, to the laminated paper packaging  
25 system, e.g. to the frame-like member (11), thereof.

In one embodiment of the invention, section (6) of the connector device adapted to be connected, e.g. sealably connected, to the laminated paper packaging system, comprises at least one triggering, e.g. actuation, system (16) capable of interacting with the opening, e.g.  
30 breaking, system (15) of the laminated paper packaging system (4) to shift it in the direction of the closure system (10), e.g. the barrier layer, provoking its opening, e.g. its breakage. In one embodiment of the invention, the triggering, e.g. actuation, system (16) may provoke movement of the opening, e.g. breaking, system (15) of the laminated paper packaging system from the first position to the second position as defined hereinabove, upon

connecting, e.g. sealably connecting, the connector device to the laminated paper packaging system. Such a triggering system may be an extending, e.g. a downwardly extending, system. It may consist of or comprise at least one means, e.g. arm or cam, capable of interacting with the opening, e.g. breaking, system (15) of the laminated paper packaging system (4), for example by leverage or reverse thread, e.g. screw thread. Such triggering systems are known to one skilled in the art. Preferably the triggering, e.g. actuation, system (16) of the connector device according to the invention is of the type of the actuation system associated with spin® cap or stream® cap, e.g. as described in EP0947433, EP1088765, EP1262412, US6,223,924, US6,422,412 or US6,382,462 which are incorporated herein by reference. In one embodiment of the invention, such a triggering system may be recessed from the closure system, e.g. the barrier layer, of the laminated paper packaging system to ensure that it provokes the opening, e.g. breaking, of the closure system, e.g. the barrier layer, only when the connector device is connected, e.g. sealably connected, to the laminated paper packaging system.

According to the invention, after being opened, e.g. broken, the closure system (10), e.g. the barrier layer, of the laminated paper packaging system (4) may be prevented from interfering with the flow of the composition contained in the laminated paper packaging system (4), for example by using opening means, e.g. a single cutter movable in spiral, as described in EP1088765, which is hereby incorporated by reference, or by any other suitable means known in the art.

According to the present invention, the connector device may comprise a tamper-proof system adapted to indicate that the laminated paper packaging system has been connected, e.g. sealably connected to the connector device, e.g. has been opened. Such a tamper-proof system may comprise an indicator member associated with section (6) of the connector device by breakable connection, e.g. by means of bridges, which connection may be permanently or irreversibly broken when the connector device is connected, e.g. sealably connected, to the laminated paper packaging system, e.g. to the frame-like member thereof (not shown). Such tamper-proof systems are known to one skilled in the art, and are described e.g. in US 6,223,924 or EP0947433, which are hereby incorporated by reference. In another embodiment of the invention, the tamper-proof system may comprise means provided in the connector device, e.g. in the tubular member associated with the connector device, such means being adapted to move unidirectionally over the closure system of the

laminated paper packaging system, e.g. over the frame-like member of the closure system. Such means may comprise indentations, e.g. indentations configured in a saw-tooth manner adapted to move unidirectionally over e.g. a ratchet pawl provided in the frame-like member of the closure system, thereby preventing removal of the connector device from the  
5 laminated paper packaging system. Such means are known to one skilled in the art and are described e.g. in EP0947433, which is hereby incorporated by reference.

The tightness of fit between the connector device (1) and the laminated paper packaging system (4) may be ensured by means (19), e.g. systems, known in the art, e.g. by  
10 gasket, by foam or elastomere, by direct top contact, or by so-called "olive tightness type", e.g. such as that present in the thread caps of bottles containing carbonated beverages. It will be appreciated that one skilled in the art is fully enabled to select a suitable tightness system.

15 According to the invention, the material of the connector device may be capable of forming a seal, e.g. airtight and/or liquid-tight seal, with the material from which the feeding line of the enteral administration set is made.

In a further embodiment of the invention, the connector device may be reversibly or  
20 permanently, e.g. irreversibly, connected to the enteral administration set, e.g. to the feeding line of the enteral administration set. The permanent, e.g. irreversible, connection of the connector device to the feeding line may be made by methods including but not limited to application of hot melt adhesive, e.g. glue, heat induction, ultrasonic welding and friction welding or any other methods as known in the art. The connector device may be molded to  
25 the feeding line of an enteral administration set to form one single unit.

The connector device of the present invention may be made from a plastic or polymeric material, including but not limited to polyolefin, e.g. polypropylene or polyethylene. The connector device of the present invention may be made from a material that has low  
30 permeability to oxygen. In one embodiment of the invention, the connector device may be opaque. Alternatively, the connector device of the present invention may be substantially transparent, or may comprise a portion which is substantially transparent, e.g. section (5) adapted to be connected to the enteral feeding line or part of the section (5).

The connector device of the present invention may be manufactured by molding technology, e.g. injection.

5 According to the invention, a cap or a seal may be placed over the external ends of the connector device, to prevent contamination of the connector device before use. For example, a cap may be thread, e.g. screw thread, to section (5) of the connector device adapted to be connected to the feeding line and/or to section (6) of the connector device adapted to be connected to the laminated paper packaging system. Such a cap may be removed before connecting the connector device to the feeding line and/or to the laminated paper packaging system.  
10

The connector device as described hereinabove may also be reversibly or permanently, e.g. irreversibly, connected to the laminated paper packaging system. The irreversible connection of the connector device to the laminated paper packaging system may involve locking means provided in the connector device, e.g. in the tubular member associated with the connector device, e.g. as described in EP0947433, which is hereby incorporated by reference.  
15

Hence, the present invention also pertains to a device comprising a connector device as hereinabove described, e.g. connected, e.g. sealably connected, e.g. reversibly or permanently connected, to an enteral administration set, e.g. the feeding line of an enteral administration set. The connector device as described hereinabove may be sterilized when connected to the feeding line, e.g. together with the feeding line. Alternatively, it may be sterilized separately from the feeding line.  
20

25 In another aspect the present invention pertains to a device comprising a connector device as hereinabove described, e.g. connected, e.g. sealably connected, e.g. reversibly or permanently connected, to a laminated paper packaging system, e.g. a Tetra Brik® or Tetra Pak®.  
30

In a further aspect of the invention, there is provided a device comprising a connector device as hereinabove described, an enteral administration set, e.g. the feeding line of an enteral administration set, and a laminated paper packaging system, e.g. Tetra Brik® or Tetra Pak, wherein the connector device may be connected, e.g. sealably connected, e.g.

reversibly or permanently connected, to the enteral administration set and/or the laminated paper packaging system.

In another aspect of the invention, there is provided an enteral administration set 5 connected, e.g. sealably connected, e.g. reversibly or permanently connected, to a laminated paper packaging system through a connector device as hereinabove described.

In a further aspect of the invention there is provided a system, e.g. closed, e.g. aseptic system comprising:

- 10 (a) an enteral administration set, e.g. as described herein, e.g. including a drip chamber,
  - (b) a laminated paper packaging system (4), e.g. as described herein, and
  - (c) a connector device (1), e.g. as described herein, connecting the enteral administration set to the laminated paper packaging system (4), and
- 15 permitting flow from the laminated paper packaging system to the enteral administration set, which connector device comprises means to simultaneously open the laminated paper packaging system when connected, e.g. releasably connected, thereto. Optionally, such connector
- 20 device may comprise venting means;
- hereinafter referred to as system of the invention.

As used herein, the term "aseptic" means free of microorganisms, e.g. substantially free of microorganisms, e.g. when in use.

25 In one aspect of the invention the means for opening the laminated paper packaging system may be the means, e.g. section, adapted to fit, e.g. adapted to be connected, e.g. sealably or releasably connected, to the laminated paper packaging system. The means of the connector device of the invention for opening the laminated paper packaging system and connecting to the laminated paper packaging system may be in form of a spike (20), e.g. a

30 cannula, e.g. a vented spike or cannula, as conventionally available, e.g. with enteral feeding lines. The spike may be of any shape, length or diameter, e.g. circular or rectangle, e.g. of a length of about 0.5 to about 10 cm, e.g. about 0.5 to about 5 cm, e.g. about 3.5 cm. It comprises a fluid passageway to permit flow of the medical or nutritional fluid from the laminated paper packaging system to the enteral administration set. The spike may have an

air passageway next to the fluid passageway. The fluid passageway may be of the same length or of shorter length compared to the air passageway. It may be of shorter length than the air passageway, e.g. the fluid passageway may be of a length of about 0.5 to about 5 cm, e.g. about 0.5 to about 3 cm, e.g. about 1 cm, e.g. to permit complete emptying of the laminated paper packaging system, e.g. when placed in an inverted orientation. The tightness of fit between such connector device comprising a spike (20) and the laminated paper packaging system may be ensured by a bonding foil or foam or rubber liner, e.g. having a tacky surface, sealed or glued to the spike (19). The bonding foil or foam or rubber liner may comprise a protection film to be removed, e.g. peeled off, before use. According to the invention a tightness to withstand a force of 15 N during a testing time of 15 seconds may be provided. Such means providing tightness fit, may further provide visible tamper signal indicating that the connector device has been connected to, e.g. releasably or sealably connected to, and/or has opened the laminated paper packaging system.

The laminated paper packaging system, e.g. with aluminum foil laminated paper board packaging system, may comprise a hole (21) in the paper board, e.g. a straw hole, for connecting the enteral administration set to the laminated paper packaging system through the connector device as hereinabove described, e.g. comprising a spike (20). The hole may be covered by a pull tab (18), to be removed, e.g. peeled off, before use, e.g. to ensure that the outer surface of the aluminum foil (17) remains aseptic. Such hole may be of any suitable shape or dimension, e.g. circular or rectangle.

In a further aspect, the laminated paper packaging system (4) may be partly transparent, e.g. may comprise a transparent window, e.g. to permit visual, e.g. quantitative and/or qualitative, control of the contents of the laminated paper packaging system. The laminated paper packaging system may be of any suitable size, e.g. for quantities of flowable materials of up to 5 liters, e.g. 50 ml to 2 liters, e.g. 500 ml or 1 liter. In use with a gravity set, the laminated paper packaging system may be placed in an inverted orientation, for instance by suspension within a conventional transparent, e.g. plastic, bag or container, vertically situated to allow flow under gravity.

The system of the invention may be used with a pump set, e.g. when a venting means, e.g. an air passageway, is not present.

According to the invention, the connector device, the device or system as hereinabove described may be sterilisable, e.g. retortable or sterilisable by ethyleneoxide (ETO), gamma-radiation, beta-radiation, peroxide or any other suitable agent, e.g. chemical agent, known to one skilled in the art.

5

In yet a further aspect the present invention, there is provided a use of a laminated paper packaging system in enteral tube feeding, which use comprises connecting, e.g. sealably connecting, e.g. directly connecting, a laminated paper packaging system to an enteral administration set through the connector device as hereinabove described.

10

According to the invention there is further provided a method of enterally administering to a patient in need thereof a medical or nutritional composition contained in a laminated paper packaging system, which method comprises connecting, e.g. sealably connecting, the feeding line of an enteral administration set to the laminated paper packaging system through a connector device as hereinabove described, e.g. using a gravity set with roller clamp or a pump set. Such sets are known to one skilled in the art.

15

In a further aspect there is provided a method for connecting, e.g. releasably connecting, the connector device as described herein, e.g. the connector device connected to an enteral administration set, to a laminated paper packaging system, which method comprises

20

- (a) removing a seal or cap from the laminated paper packaging system, and
- (b) simultaneously opening or breaking of the closure system of the laminated paper packaging system when the connector device is connected, e.g. releasably connected, thereto.

25

The connector device and the device as hereinabove described are easy to handle and are inexpensive to manufacture. They allow convenient, safe, and economically advantageous administration of a medical or nutritional composition to a patient in need thereof.

30



Claims

1. A connector device for an enteral administration set and a laminated paper packaging system comprising:
  - 5 (a) means adapted to fit to the enteral administration set,
  - (b) means adapted to fit to the laminated paper packaging system,
  - (c) means adapted to allow the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system to the enteral administration set through the connector device, and optionally
  - 10 (d) venting means to selectively allow outside air to flow, which venting means optionally comprise means to allow filtration of the air.
2. A connector device for an enteral administration set and a laminated paper packaging system comprising a closure system, which connector device comprises:
  - 15 (a) means adapted to fit to the enteral administration set,
  - (b) means adapted to fit to the laminated paper packaging system,
  - (c) a passageway to allow the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system to the enteral administration set through the connector device, and optionally
  - 20 (d) means adapted to provoke the opening or breakage of the closure system, when the connector device is connected to the laminated paper packaging system, and optionally
  - (e) venting means to selectively allow outside air to flow, which venting means optionally comprise means to allow filtration of the air.
- 25 3. The connector device according to claim 2 comprising means (d) adapted to provoke the opening or breakage of the closure system, wherein such means comprise at least one cutting means.
- 30 4. The connector device according to claim 2 comprising a triggering system adapted to provoke the opening or breakage of the closure system of the laminated paper packaging system.

5. The connector device according to claim 4 wherein the triggering system is a leverage system:

6. A connector device for an enteral administration set and a laminated paper packaging system comprising a frame-like member, which connector device comprises:

- (a) means adapted to fit to the enteral administration set,
- (b) means adapted to fit to the laminated paper packaging system,
- (c) a passageway to allow the flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system to the enteral administration set through the connector device,
- (d) means adapted to trigger a breaking system incorporated into the frame-like member of the laminated paper packaging system, when the connector device is connected thereto, and optionally
- (e) venting means to selectively allow outside air to flow, which venting means optionally comprise means to allow filtration of the air.

7. A connector device for a laminated paper packaging system comprising a closure system, which connector device comprises:

- (a) means adapted to fit to the laminated paper packaging system,
- (b) means adapted to provoke the opening or breakage of the closure system, when the connector device is connected to the laminated paper packaging system,
- (c) a passageway to allow flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system through the connector device, and optionally
- (d) venting means to selectively allow outside air to flow, which venting means optionally comprise means to allow filtration of the air.

8. A connector device for a laminated paper packaging system comprising a frame-like member, which connector device comprises:

- (a) means adapted to fit to the laminated paper packaging system,
- (b) means adapted to trigger a breaking system incorporated into the frame-like member of the laminated paper packaging system, when the connector device is connected to the laminated paper packaging system,

(c) a passageway to allow flow of a composition contained in the laminated paper packaging system from the laminated paper packaging system through the connector device, and optionally.

(d) venting means to selectively allow outside air to flow, which venting means optionally comprise means to allow filtration of the air.

9. A connector device suitable for connecting an enteral administration set to a laminated paper packaging system.

10. A connector device for a laminated packaging system and optionally an enteral administration set, adapted to simultaneously open, or provoke the opening of, the laminated paper packaging system when being connected thereto.

11. The connector device according to any preceding claim having an internal diameter of between about 1.0 and about 3.5 cm.

12. The connector device according to any preceding claim wherein the laminated paper packaging system is Tetra Brik® or Tetra Pak®.

13. The connector device according to any preceding claim adapted to sealably fit to the laminated paper packaging system and to the enteral administration set.

14. Use of a laminated paper packaging system in enteral tube feeding, which use comprises sealably connecting a laminated paper packaging system to an enteral administration set through a connector device as described in any one of claims 1 to 13.

15. A device comprising an enteral administration set and the connector device of any one of claims 1 to 13.

16. A device comprising a laminated paper packaging system and the connector device of any one of claims 1 to 13.

17. The device according to claim 16 wherein the laminated paper packaging system is Tetra Brik® or Tetra Pak®.

18. An enteral administration set connected to a laminated paper packaging system through a connector device of any one of claims 1 to 13.

19. Method of enterally administering to a patient in need thereof a medical or nutritional composition contained in a laminated paper packaging system, which method comprises sealably connecting the feeding line of an enteral administration set to the laminated paper packaging system through a connector device or device according to any one of claims 1 to 15 and allowing the composition to flow through the connector device from the laminated paper packaging system to the feeding line.

20. The method according to claim 19 wherein the laminated paper packaging system is Tetra Brik® or Tetra Pak®.

21. A connector device, device or enteral administration set as claimed in any one of claims 1 to 13 or claims 15 to 18, substantially as hereinbefore described with reference to any one of the accompanying figures.

22. A closed system comprising

(a) an enteral administration set,

(b) a laminated paper packaging system, and

(c) a connector device releasably connecting the enteral administration set to the laminated paper packaging system, and permitting flow from the laminated paper packaging system to the enteral administration set, which connector device comprises means to simultaneously open the laminated paper packaging system when releasably connected thereto.

23. A method for releasably connecting the connector device of any one of claims 1 to 13 to a laminated paper packaging system, which method comprises

(a) removing a seal or a cap from the laminated paper packaging system, and

(b) simultaneous opening or breaking of the closure system of the laminated paper packaging system when the connector device is releasably connected thereto.

ABSTRACT

5 The present invention relates to a connector device suitable for connecting an enteral  
administration set to a laminated paper packaging system comprising enterally administrable  
medical or nutritional food.

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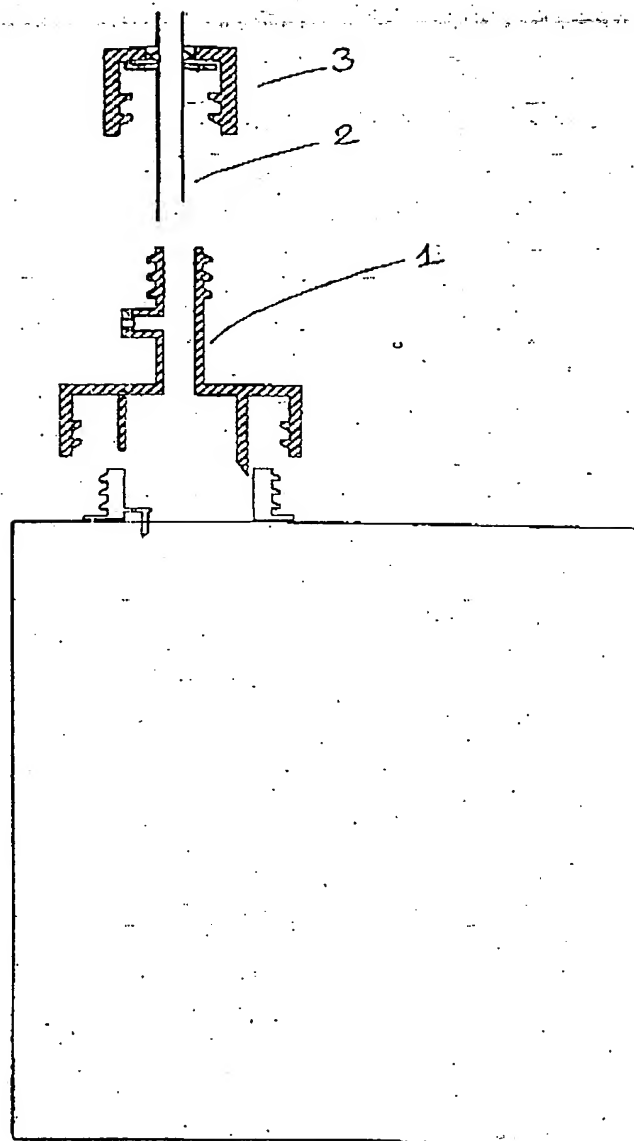
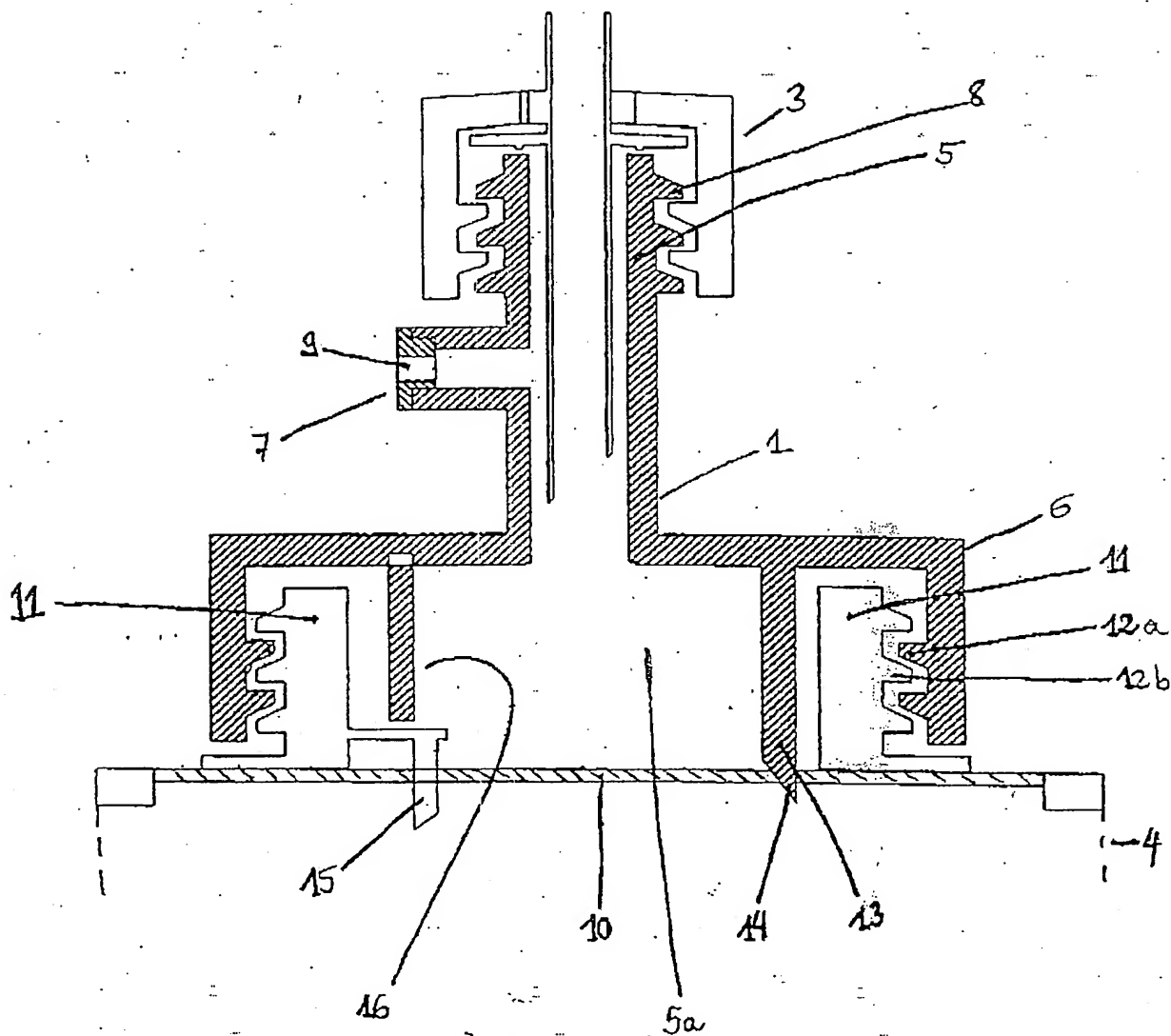


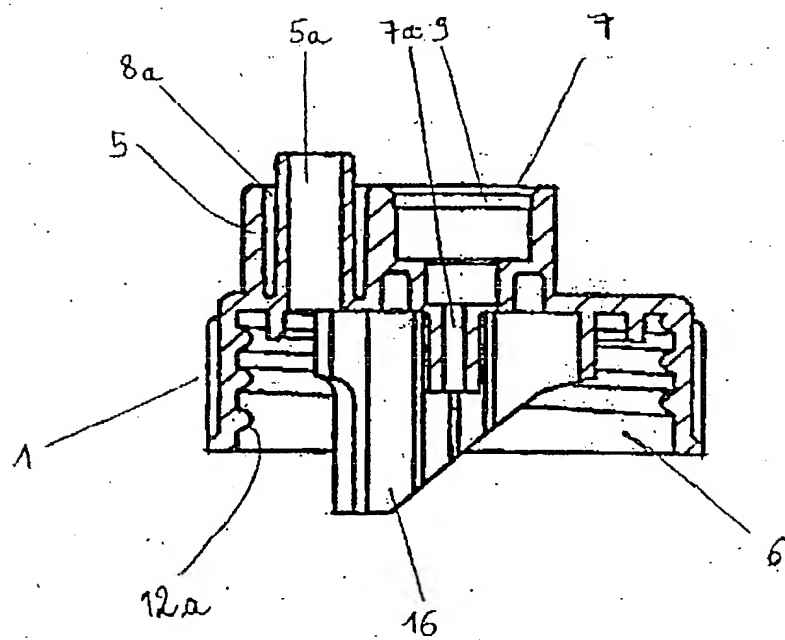
FIG. 1

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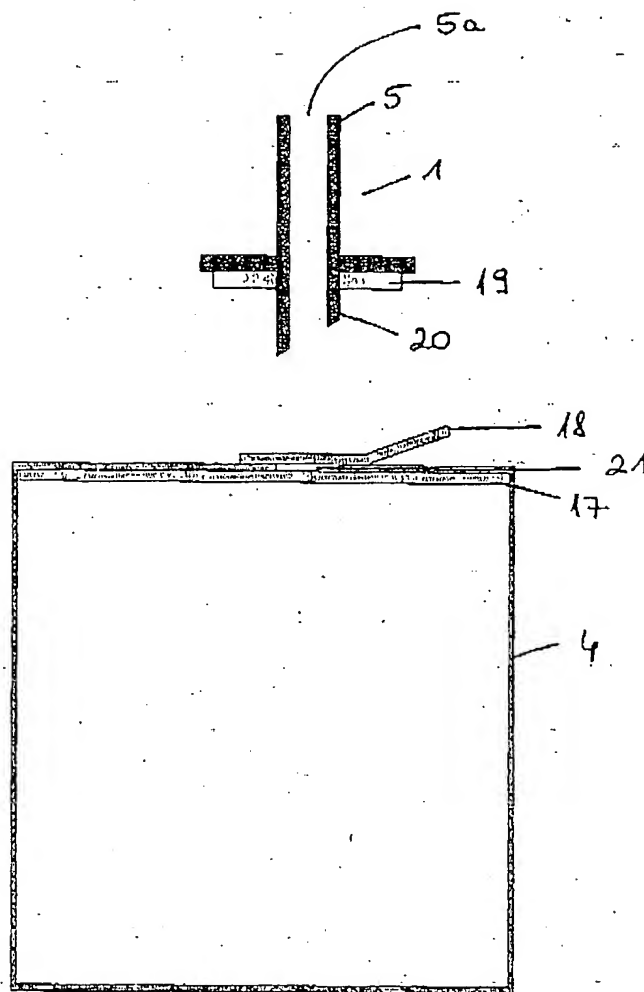


FIG. 4

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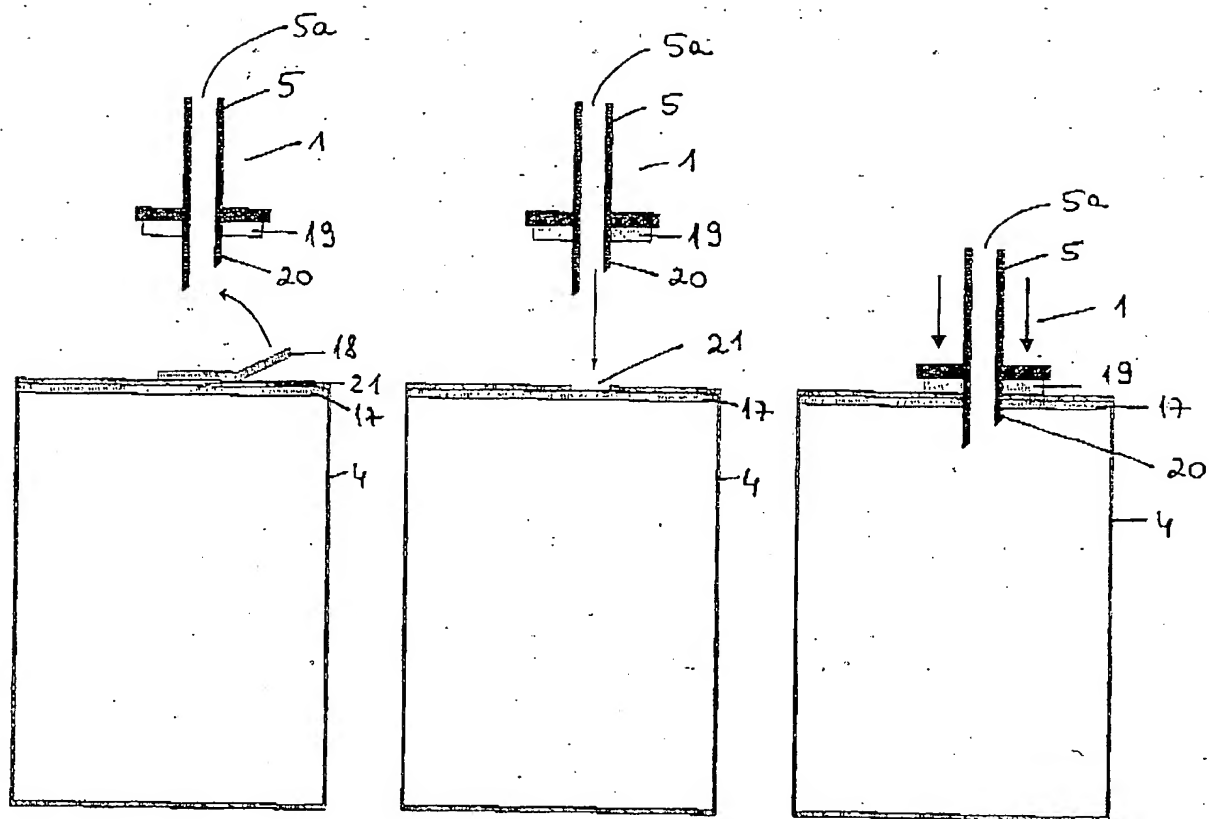


FIG. 5

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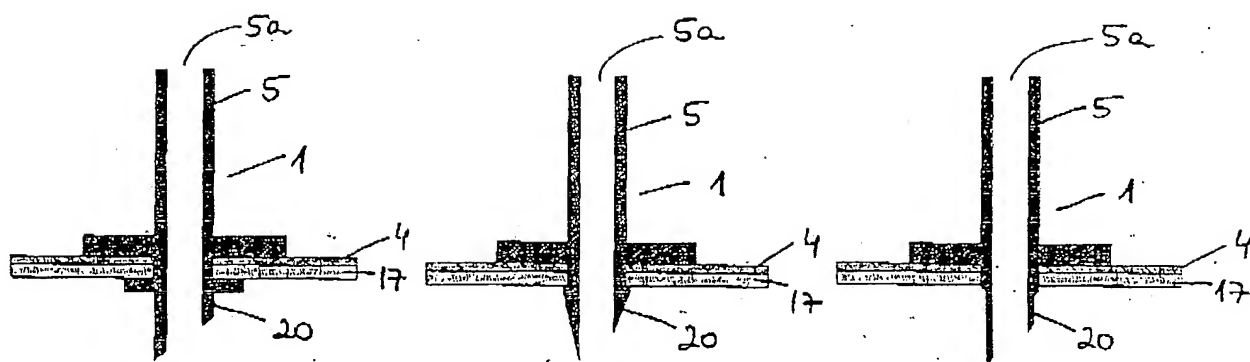


FIG. 6

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